

5 **Methods for Managing Infection Risk Incident to Surgical Procedures in Health Care Provider Environments**

FIELD OF THE INVENTION

The present invention relates to methods of managing the risk, occurrence, or both the risk and occurrence of surgical site infection incident to various surgical procedures. The invention also relates to devices for managing such risks, including software-encoded and network delivered devices.

BACKGROUND OF THE INVENTION

Over the past number of decades, health care environments have witnessed a nearly forty percent rise in nosocomial infections arising from the delivery of surgical procedures. This increase persists despite advances in medicine and a reduction in the number and size of hospitals. Many factors are believed to contribute to the infection rise, including the prevalence of larger intensive care units ("ICUs"), fewer nurses, the increased severity of patient illness, the increased numbers of immunocompromised patients, and the scarcity of infection control practitioners.

Surgical site infections ("SSIs") represent the third most frequently reported nosocomial infection, accounting for between 14 and 16 percent of all nosocomial infections among hospitalized patients. Among surgical patients, SSIs are the most common nosocomial infections accounting for 38 percent of such infections in this population.

The cost of a SSI to a surgical patient can be significant. The incidence of such an infection can result in extended lengths of stay, increased use of antibiotics, added pain, and longer recovery periods. Nosocomial infections also lead directly to 19,000 deaths each year and are a contributing factor to more than 80,000 additional deaths annually.

SSIs also represent additional costs to the health care system; under the majority of managed care contracts, healthcare systems are not reimbursed for the additional costs of nosocomial infections. Nosocomial infections cost health care systems \$4.5 billion per

year. On average, a single SSI outbreak costs \$3152 and causes an additional 7.3 days of hospital stay.

Most importantly, nosocomial infections are usually preventable. With over 27 million surgical procedures performed in the U.S. each year, reducing the risk of SSIs becomes a matter of saving lives. There exists, therefore, a need for an effective and easily administerable method of managing the risk of nosocomial infections in a health care delivery facility.

SUMMARY OF THE INVENTION

Briefly, in one aspect, the present invention provides a method for managing the occurrence or risk of surgical site infection incident to a surgical procedure, the method comprising:

- (a) identifying a plurality of stages of operative care, including at least a preoperative stage, an intraoperative stage, and a postoperative stage;
- (b) identifying one or more points-of-care within each identified stage of operative care;
- (c) for each point-of-care, identifying one or a plurality of sources of measurable risk of surgical site infection;
- (d) for identified surgical site infection risks, identifying at least one practice for either or both managing or reducing the risks, either individually for each risk or collectively for more than one risk; and
- (e) aligning the identified practice or practices within each point-of-care to provide a set of sequential practices throughout each of the stages of operative care in a manner that provides a desired management of the overall occurrence or risk of surgical site infection.

In another aspect, the present invention provides a method for managing the risk or occurrence of surgical site infection incident to a surgical procedure, the method comprising: (a) identifying a plurality of health care delivery practices appurtenant to a surgical procedure that contribute to or pose a risk of surgical site infection; (b) grouping one or more of the identified practices into a plurality of points-of-care; (c) aligning,

monitoring and managing the operation of the points-of-care to provide a desired management of the overall occurrence or risk of surgical site infection.

In another aspect, the invention provides a system for managing the risk or occurrence of surgical site infection incident to a surgical procedure, the method comprising:

- (a) identifying a plurality of stages of operative care, including at least a preoperative stage, an intraoperative stage and a postoperative stage;
- (b) identifying one or more points-of-care within each identified stage of operative care;
- (c) for each point-of-care, identifying one or a plurality of health care delivery practices that pose a source of measurable risk of surgical site infection;
- (d) identifying one or more compliance indicators for one or a plurality of health care practices within each point-of-care whereby there is provided the ability to monitor the compliance indicators;
- (e) aligning the health care delivery practices with the compliance indicators to provide a perioperative process map of delivery practices spanning the plurality of stages of operative care.

In still another aspect, the invention provides a system for managing the risk or occurrence of surgical site infection incident to a surgical procedure, the system comprising: (a) a perioperative process map of practices for the delivery of the surgical procedure, the map comprising a plurality of health care delivery practices and one or more indicators of compliance with the one or more health care practices; and (b) means for monitoring the compliance indicators to achieve a desired level of management of the risk of surgical site infection for the surgical procedure.

In still other aspects, the present invention provides devices, including software-encoded and computer network delivered devices, useful in carrying out the methods and systems of the invention.

The methods and systems of the invention can be utilized to manage or control the risk of surgical site infection and as such, they can be used to follow the course of a surgical patient from preoperative assessment when the surgical decision is made through

postoperative recovery to a point when the patient is no longer at risk of infection. Moreover, the invention provides a description of actions performed by the patient and health care team involved in the patient's operation and can apply to any perioperative practice setting. Thus used, the methods and systems of the invention provide streamline approaches to a cost effective standard of care.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a schematic perioperative process map according to the methods and systems of the invention.

FIG.2 illustrates one embodiment of a perioperative process map developed according to the methods and systems of the invention.

FIG.3 provides a detailed schematic representation of one possible alignment of stages of a perioperative process map of the invention.

FIG. 4 illustrates one embodiment of the alignment of the stages of a perioperative process map of the invention.

FIG. 5 illustrates an embodiment of a perioperative process map utilizing compliance indication techniques according to the invention.

FIG. 6 illustrates one possible application of the use of compliance indication according to the invention to a postoperative stage of care.

FIG. 7 illustrates one possible implementation of compliance indication to the methods and systems of the invention.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

The present invention provides methods and systems for managing the risk and/or occurrence of surgical site infection. In their most essential respect, the methods and systems comprise utilization of a map of health care delivery practices appurtenant to a surgical procedure, or a so-called perioperative process map. These maps can span practices delivered preoperatively, intraoperatively and post-operatively, or can be concentrated on only one or several of the stages of delivery of a surgical procedure. The perioperative maps, once envisioned, can be used in a healthcare environment to effectively manage, and in some embodiments control, the delivery of practices to reduce

the risk and occurrence of surgical site infection. In so doing, the methods of the invention also impact the ability of a healthcare provider to manage other desired outcomes, including cost reduction, cost control, patient satisfaction, employee health, and employee welfare.

5 According to the invention, a perioperative process map is constructed for a surgical procedure of interest by identifying a plurality of stages for that surgical procedure. Depending on the scope of the desired process map, the stages may include one or more of a preoperative stage, an intraoperative stage, and a postoperative stage. Each stage of the procedure includes one or more points-of-care. These points-of-care
10 typically comprise one or a plurality of health care practices that are delivered in relatively close proximity to one another either in time or in location. For example, a pre-operative point-of-care may include multiple preoperative activities, including administration of antibiotics, hair removal, *etc.*, while a postoperative point-of-care may include instrument reprocessings and mechanics of environmental cleaning. While sound health care
15 management requires that some delivery activities customarily take place in a given general order, it will be understood that each health care provider may incorporate different activities into its delivery practices, may bundle them differently into different points-of-care, and may place different activities in different sequential relation. For purposes of the present invention, however, a point-of-care for a given health care provider
20 (and for a given surgical procedure) will include one or more closely related activities drawn together either because of their close relationship to one another in time or in place, or by their common purpose (*e.g.*, pre-surgical patient preparation).

A point-of-care itself, combined with the activities within it, will present one or more measurable sources of infection risk. These sources may be attributable to a fixed
25 environment. For example, the layout and ventilation of a particular surgical suite may present unique (and somewhat unalterable) sources of infection risk, while the relative proximity of the location of the administration of preoperative care to the location of a surgical suite may pose other unique risks. Other sources of risk may be more variable (and more controllable). For example, the time allowed to elapse between the
30 administration of pre-operative regimes and the administration of the surgical procedure may be a parameter subject to control.

The methods and systems of the invention provide a mechanism to align the otherwise disconnected collection of activities necessary for the performance of a surgical procedure, categorize them according to their shared infection risk, and manage them pursuant to a common protocol for infection risk management.

Figure 1 illustrates a generic perioperative process map according to the invention. The delivery of a surgical procedure (*e.g.*, a coronary artery bypass graft) is segregated into N number of stages. Stage 1 comprises N points-of-care 10, 20, 30 and 50. Within each Point-of-Care N , there is identified N sources of risk 40. Stage 2 comprises a single point-of-care 60 within which there are N sources of risk 70. Similarly, Stage N comprises N points-of-care (80 and 100) comprising various sources of risk, including N sources of risk 90.

Figure 2 illustrates another, more specific, example of a perioperative process map according to the invention. Here, the delivery of a surgical procedure is divided into three stages, a preoperative stage 102, an intraoperative stage 104 and a postoperative stage 106. The pre-operative stage comprises four points-of-care: preoperative assessment 110, operation scheduling 112, surgical patient preparation 114 and patient entry 116. Each of these points-of-care, in turn, comprise one or more activities that pose one or more measurable sources of infection risk. Point-of-care 110 comprises a single source of risk 124. Point-of-care 114 (surgical patient preparation) comprises multiple sources of risk 128. In a similar fashion, the second stage, intraoperative care 104, comprises a point-of-care 118 (surgery) within which there are seven sources of risk 132. Lastly, postoperative stage 106 comprises two points-of-care. Point-of-care 120 (patient exit) comprises five sources of risk 143 and Point-of-care 122 (patient follow-up) comprises two such measurable risk sources 136. It will be understood that the map of Figure 1 represents and exemplifies the general structure of the perioperative process maps of the invention as applied to one possible scenario in a health care provider's facility. The map provides a tool for: (1) identifying measurable sources of infection risk (that is, those that are generally statistically significant and about which data can be gathered); and (2) aligning those sources along a continuum to set forth, for an individual provider, a generally sequential series of practices that when taken and managed together can be used to manage and/or control the risk of infection.

Figure 3 provides a more detailed illustration of the application of a process map to one stage of a surgical procedure. Stage 300 comprises points-of-care 310 and 320. Point-of-care 310 comprises sources of risk 330, 340, 350 and 360, and source of risk 330, in turn, comprises practices 370, 380 and 390. Figure 3 thus illustrates the generalized process map as applied, in particular, to one significant source of infection risk. Here, prudent health care judgment is applied to identify three practices delivered in one of the points-of-care that contribute to the subject source of risk. These practices are ones about which data can be generated (*e.g.*, to identify whether or not the practice or standard was complied with or to identify the relative quality of the delivery of that practice). A more complete perioperative process map would identify a continuum of such practices.

Figure 4 provides an illustration of the generalized map of Figure 3 to one exemplary health care facility. A surgical procedure having a Postoperative stage 400 comprises two points-of-care: Patient exit from the operating room 410 and patient surgical follow-up 420. The patient exit point-of-care has five sources of measurable infection risk: risks realized from instrument reprocessing (430), soiled linen handling and removal (440), environmental cleaning (450), wound management (460) and patient education (470). In the example of Figure 4, four practices are found to contribute to the risks attendant to wound management. These are: proper handwashing (462), administration of sterile dressings (464), dressing changing practices (466) and drain removal (468). These practices are felt to govern, in a meaningful and statistically significant way, the risks of infection for wound management in a particular hospital setting. This is not to imply that other practices (*e.g.*, storage practices of sterile dressing) are not necessary for proper wound management, nor that such other practices may be found to be significant in another hospital setting.

The methods of the invention are generally adopted after a thorough review of a given health care facility in which the map is to be employed, most typically a traditional hospital environment. This initial review employs a prudent and knowledgeable judgment to ascertain, for a subject facility and for a given surgical procedure, what practices are to be scrutinized and categorized. Typically practices are identified according to one or several of the following characteristics: (a) practices that contribute to or pose a significant risk of infection; (b) practices that are readily measurable and controllable, (c) practices

that represent or contribute a significant cost for the health care provider; and (d) practices that affect patient comfort and satisfaction. The practices that ultimately form the basis of the perioperative process map are reviewed for such characteristics and are selected according to criteria unique to the desires of the intended user. One hospital may accord
5 different weight than another to cost control, or, within a single hospital environment, one surgical procedure may be subject to different cost considerations and constraints than another.

Once the practices are selected according to a desired set of criteria, the practices can be grouped according to their proximity with one another into points-of-care. For
10 example, those practices that are delivered at or about the same time can be grouped together, as can those practices that are delivered in the same place or that are delivered for a common purpose or as a single regimen. Once grouped together, these practices are aligned into points-of-care and stages of care into a perioperative process map in a manner that affords a continuum of practices across one or multiple stages of care. In this way a
15 perioperative process map can be constructed that includes all stages of surgical care, spanning from the time a surgical patient is identified as a candidate for surgery until that patient has fully recovered from the delivery of the surgical procedure and is no longer at risk for surgical site infection. This map may be referred to as a home-to-home map.

The range of possible sources of risk and health care delivery practices subject to
20 the construction of a perioperative process map is large and, as noted above, varies from one health care facility to another and from one surgical procedure to another. It is also important to note that the delivery of a given practice may alone pose a measurable source of infection risk. In such a case, a single practice may be both a source of infection risk and a practice for managing the risk (*i.e.*, the practice must be done in a manner that
25 minimizes the risk it poses). Alternatively, there may be a single source of risk (*e.g.*, risk associated with linen handling) that is appropriately managed by multiple practices (*e.g.*, laundering, use of disposable linens, handling of soiled linens, *etc.*).

Table 1 below, shows some of the practices and sources of risk associated with a patient undergoing a surgical procedure.

TABLE 1

Points-of-Care		Risk Sources/Practices
5	<i>Home</i>	Exercise
		Diet
		Medications
		Habits (smoking, <i>etc.</i>)
		Family & health history
10	<i>Healthcare Entry</i>	Patient history and physical
		Scheduling
		Pre-existing infection treatment
		Health care professional briefing
15	<i>Preoperative Assessment</i>	Patient education and instruction
		Diagnostic testing
		Laboratory test administration
		Patient education and instruction
20	<i>Admission</i>	Patient risk assessment and management
		Diagnostic studies
		Patient education and instruction
25	<i>Preoperative Preparation</i>	Preoperative shower (antiseptic or other)
		Hair removal method
		Written instructions
		Antibiotic prophylaxis
30		Instrument processing
		Line insertions
		Skin preparation
		OR layout and set-up
		Equipment check
		Physician and nurse preparation
		Surgical Attire
		Housekeeping

5	<i>Intraoperative Procedures</i>	Draping
		Anesthesia administration
		Sterilization
		Antibiotic redosing
		OR traffic handling
		Instrument and supply transport
		Surgical field sterility
		Duration of operation
		Room cleaning and filtering
		Surgical technique
		Aseptic technique
		Wound closure
10		Risk stratification
15	<i>Postoperative Recovery</i>	Patient education and instruction
		Room cleaning and filtering
		Instrument reprocessing and storage
		Needs assessment
		Skin integrity
		Wound care
		Soiled attire and linen handling
20		
25	<i>Discharge</i>	Patient education and instruction
		Patient compliance in diet
		Patient compliance in medication
		Patient compliance in wound management
30	<i>Physician Follow-up</i>	Health assessment
		SSI surveillance
		Scheduling of routine care
		Health promotion
		Infection outbreak management
35	<i>Home</i>	Healthy living

40 In some embodiments, the methods and systems of the invention incorporate avenues for monitoring the level and degree of compliance with the perioperative process map in practice settings. Briefly, according to this aspect of the invention, one or more of the health care delivery practices and/or sources of risk are monitored with one or more compliance indicators. These compliance indicators typically will measure or mark the delivery of the subject practice or practices (or the management of the source or sources of risk) against an accepted standard. A compliance indicator may, for example, ask whether

or not a practice has been performed, or it may seek a qualified or quantified measure of the quality of the performed practice. Standards of care against which compliance indicators may be selected are drawn from any number of accepted protocols, guidelines, standards or clinical pathways, including those identified below, which are incorporated by reference herein in their entirety.

American Association of Nurse Anesthetists (AANA), *Infection Control Guide*, Park Ridge, IL: AANA; revised 1997.

- 10 American College of Surgeons, *Care of the Surgical Patient, Volume 2: Elective Care*, New York, NY: Scientific American; 1988-1993.

- 15 American Institute of Architects, Academy of Architecture for Health, with assistance from the U.S. Department of Health and Human Services, *Guidelines for Design and Construction of Hospital and Health Care Facilities*, Washington, D.C.: AIA Press; 1996.

- 20 American Society of Anesthesiologists (ASA), Committee on Occupational Health of Operating Room Personnel and Task Force on Infection Control, *Recommendation for Infection Control for the Practice of Anesthesiology*, 2nd ed., Available at www.asahq.org/profinfo/infection.

- 25 Association for Professionals in Infection Control and Epidemiology (APIC), Larson EL. APIC guideline for handwashing and hand antisepsis in health care settings, *Am J Infect Control*. 1995; 23:251-269.

- Larson E. Guideline for use of topical antimicrobial agents. *Am J Infect Control*. 1988; 16:253-266.

- 30 Lee TB, Baker OG, Lee JT, Scheckler WE, Steele L, Laxton CE. Recommended practices for surveillance. *Am J Infect Control*. 1998; 26:277-288.

Martin MA, Reichelderfer M. APIC guideline for infection prevention and control in flexible endoscopy. *Am J Infect Control*. 1994; 22:19-38.

- 35 Rutala WA. APIC guideline for selection and use of disinfectants. *Am J Infect Control*. 1996; 24:313-342.

- 40 Sherertz RJ, Streed SA, Gledhill KS. Surgical site infections. In *APIC Infection Control and Applied Epidemiology*. St. Louis, MO: Mosby; 1996:11-1 to 11-5.

Association for the Advancement of Medical Instrumentation (AAMI), *AAMI Standards and Recommended Practices, Volume 1.1: Sterilization*. Arlington, VA:AAMI; 1998.

Association of periOperative Registered Nurses (AORN), *Recommended Practices & Guidelines*. Denver, CO: AORN; 1999.

Centers for Disease Control and Prevention, Hospital Infection Control Practices Advisory Committee (CDC), Mangram AJ, Horan TC, Pearson ML, et al. Guideline for prevention of surgical site infection, 1999. *Am J Infect Control*. 1999; 27:97-134.

Society for Healthcare Epidemiology of America (SHEA), Consensus paper on the surveillance of surgical wound infections: The Society for Hospital Epidemiology of America, The Association of Practitioners in Infection Control, The Centers for Disease Control, The Surgical Infection Society. *Infect Control Hosp Epidemiol*. 1992; 13:599-605.

Surgical Infection Society (SIS), Page CP, Bohen JM, Fletcher JR, et al. Antimicrobial prophylaxis for surgical wounds: guidelines for clinical care. *Arch Surg*. 1993; 128:79-88.

Figure 5 illustrates the operation of a perioperative process map according to the invention that incorporates the use of compliance indicators. In Figure 5, Stage of care 500 comprises two points-of-care 510 and 520. Point-of-care 510 comprises in turn four sources of risk 530, 560, 570 and 580. Source of risk 530 is identified as having three practices 532, 542, and 552 that contribute to that risk. For each identified practice a compliance indicator is selected and measured (as indicated by steps 534, 544, and 554). As noted above, this measurement may take the form of a simple indication that a practice was performed or may represent a selection against a pre-established quality scale (e.g., a numeric scale from 1 to 10). From these measurements, reports 536, 546 and 556 may be generated. These reports may represent a simple compilation of measurement data. They may also involve or represent manipulation of the raw data, by formula or otherwise, to transform the data into a desired finished or near-finished form. These reports may then be used as inputs to data analyses 538, 548 and 558. Such data analyses can be used in any manner desired by the user. For example, the data compilations may be used simply to monitor compliance with the perioperative process map in real-time, to record historical trends in compliance, to correlate the compliance indicators with one or more indications of a desired outcome (e.g., infection rate, cost control, or patient satisfaction), or as inputs to one or more feedback process control loops. The data compilations can also be used for multiple such uses.

Figure 6 illustrates one possible application of a system employing compliance indicator measurement to a postoperative stage of care. In Figure 6, Postoperative Stage 600 comprises two points-of-care 610 and 620, patient exit from OR and patient follow-up respectively. In turn, point-of-care 610 comprises five significant sources of risk, instrument reprocessing 630, removal of soiled linen and attire 640, environmental cleaning 650, wound management 660 and patient education 690. Source 660 (wound management) comprises four practices: handwashing 662, dressing application timing 670, dressing application technique 675 and drain removal 680. According to the illustrated embodiment, compliance of each practice is measured and recorded (as indicated by reference numerals 664, 672, 677 and 682) from which reports are generated (664, 672, 677 and 682) and the resulting data is analyzed (665, 673, 678 and 683) according to the needs and desires of the user.

The methods and systems of the invention can be, in part or in whole, encoded into software or hardware. Thus, devices can be constructed which embody the perioperative process maps of the invention. Such devices may find particular utility in managing and monitoring systems of the invention that employ one or more compliance indicators and/or one or more outcome indicators (*e.g.*, patient satisfaction, infection rate, *etc.*). Such software, when used, can be encoded by any known or useful method and can utilize any known or useful software language. Figure 7 shows one possible embodiment of encoded logic. Briefly, in such an embodiment, a practice is evaluated for the significance of the risk it poses. For those risks that are determined to pose a significant infection risk, one or more compliance indicators are measured and recorded. The recorded compliance data is analyzed and compared against a standard (or rule). For any practice not in compliance, data is flagged and action must be taken (the nature of which may be determined by the user) to clear the flag.

Software-encoded devices may be used as part of an effective risk management program. Such devices can be incorporated into other software regimes, including software that tracks and manages the flow of patients throughout a health care facility. The software devices of the invention can also be used for remote monitoring of a health care facility, *e.g.*, monitoring done for the health care facility by individuals located off-

site from the facility. Such devices could operate across a computer network or via the internet.

Various modifications and alterations of this invention will be apparent to those skilled in the art without departing from the scope and spirit of this invention, and it

5 should be understood that this invention is not limited to the illustrative embodiments set forth herein.